



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment periods.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule, and for the information collection related to the proposed rule, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” that appeared in the Federal Register of January 16, 2013. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments on the proposed rule. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: The comment period for the proposed rule published January 16, 2013, at 78 FR 3646, is extended. In addition, the comment period for the information collection issues in the proposed rule, extended February 19, 2013, at 78 FR 11611, is further extended. Submit either electronic or written comments on the proposed rule by September 16, 2013. Submit comments

on information collection issues under the Paperwork Reduction Act of 1995 by September 16, 2013 (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0920 and/or Regulatory Information Number (RIN) 0910-AG36, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

#### Electronic Submissions

Submit electronic comments in the following way

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this

document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule:

Jenny Scott,  
Center for Food Safety and Applied Nutrition (HFS-300),  
Food and Drug Administration,  
5100 Paint Branch Pkwy.,  
College Park, MD 20740,  
240-402-2166.

With regard to the information collection:

Domini Bean,  
Office of Information Management,  
Food and Drug Administration,  
1350 Picard Drive,  
PI50-400T,  
Rockville, MD 20850,  
[domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 16, 2013 (78 FR 3646), we published a proposed rule entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” with a 120-day comment period on the provisions of the proposed

rule and a 30-day comment period on the information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

OMB and FDA previously received requests for a 90-day extension of the comment period for the information collection provisions of the proposed rule. We considered the requests and extended the comment period for the information collection for 90 days to make the comment period for the information collection provisions the same as that for the proposed rule-- i.e., until May 16, 2013 (Federal Register of February 19, 2013, 78 FR 11611). FDA has now received comments requesting an extension of the comment period on the proposed rule. Each request conveyed concern that the current 120-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA has considered the requests and is granting a 120-day extension of the comment period for the proposed rule. FDA believes that a 120-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. We also are extending the comment period for the information collection provisions for 120 days to continue to make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule. To clarify, FDA is requesting comment on all issues raised by the proposed rule.

## II. Paperwork Reduction Act of 1995

Interested persons may either submit electronic comments regarding the information collection to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov) or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:202-395-7285. All comments should be identified with the title "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."

### III. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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